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|-------------------------------|-------------------------------|----------------------------------|--|
| <b>Notice of Allowability</b> | <b>Application No.</b>        | <b>Applicant(s)</b>              |  |
|                               | 09/752,857<br><b>Examiner</b> | STAHLY ET AL.<br><b>Art Unit</b> |  |
|                               | Yelena G. Gakh, Ph.D.         | 1743                             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Amendment filed on 12/29/03 and Interview of 02/05/04.
2.  The allowed claim(s) is/are 81-88, 97 and 98.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 12/29/03
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date 02/05/04.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

### **DETAILED ACTION**

1. The Amendment filed on 12/29/03 is acknowledged. Claims 1-33, 35-36, 38-41, 46-48 and 50-80 are cancelled without prejudice. Claims 81-96 are pending in the Application.

### **EXAMINER'S AMENDMENT**

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Steven Scott on 02/05/04.

The application has been amended as follows:

Cancel claims 89-96 without prejudice or disclaimer.

81. (Amended) A method of screening for a new crystal form of a substance, which comprises solidifying the substance in one or more capillary spaces each independently having an inside diameter from about 0.1 mm to about 5 mm to produce at least one crystal form of the substance;

analyzing the crystal form of the substance in at least one of the capillary spaces while the substance remains in the capillary space, using at least one technique chosen from microscopic analysis, thermal analysis, diffraction analysis, and spectroscopic analysis; and classifying the crystal form by comparing the analytical results of the crystal form of the substance [produced] to those of a known crystal form or forms of the substance [to determine] and determining if the crystal form of the substance produced is new.

In the beginning of claims 82-84: before "method" change [A] to The.

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85. (Amended) A method of screening for a new crystal form of a substance, which comprises solidifying the substance in one or more capillary tubes each independently having an inside diameter from about 0.1 mm to about 5 mm to produce at least one crystal form of the substance;

analyzing the crystal form of the substance in at least one of the capillary tubes, using at least one technique chosen from microscopic analysis, thermal analysis, diffraction analysis, and spectroscopic analysis; and

classifying the crystal form by comparing the analytical results of the crystal form of the substance [produced] to those of a known crystal form or forms of the substance [to determine] and determining if the crystal form of the substance produced is new.

In the beginning of claims 86-88: before “method” change [A] to The.

97. (New) The method as claimed in claim 81, wherein the substance is solidified by solvent evaporation, cooling, heating, anti-solvent addition, gel diffusion or thin-layer deposition.

98. (New) The method as claimed in claim 85, wherein the substance is solidified by solvent evaporation, cooling, heating, anti-solvent addition, gel diffusion or thin-layer deposition.

**Claims 81-88 and 97-98 are allowed. The new numbering of claims is 1 through 9.**

The following is an examiner's statement of reasons for allowance: the Examiner's Amendment discussed with the Applicant's representative on 02/05/04 clarifies the subject matter of claims 81 and 85. Lehmann, the closest prior art related to the subject matter of claims 81 and 85 (and corresponding dependent claims) does not teach or fairly suggest searching for the new crystal forms by solidifying compounds in capillary tubes, or, alternatively, in capillary spaces when crystals are not removed from the capillary spaces for analysis.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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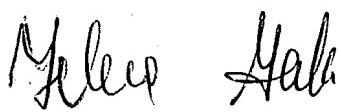
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh  
2/9/04

A handwritten signature in black ink, appearing to read "Yelena Gakh".